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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,884

10/24/2005

Bengt E B Sandberg

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EXAMINER

TONGUE, LAKIA J

ART UNIT

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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,884	Applicant(s) BENGT E B SANDBERG	
	Examiner LAKIA J. TONGUE	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 11-24 filed on March 19, 2009 is acknowledged. Claims 1-24 are currently pending. Claims 3-8, 13-18, 21, 23 and 24 have been amended. Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 11-24 are under examination.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on May 27, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

2. Claims 11 and 13 is objected to because of the following informalities: Claim 11 has multiple informalities, for example, 'com- prising' should be comprising. Claim 13 is lacking the word "of" between the words concentration and said. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rendered vague and indefinite by the use of the phrase "...a separation matrix with eliminated or reduced microbial content, the method comprising the steps of providing said separation matrix, microbially contaminated". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes "microbially contaminated", considering the matrix is suppose to have eliminated or reduced microbial content? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 13 is rendered vague and indefinite by the use of the phrase "wherein the concentration of said at least one alkyl paraben decreases with increasing alkyl number". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes a "concentration of at least one alkyl paraben decreasing with increasing alkyl number"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 14-17 and 20 are rendered vague and indefinite by the use of the terms "g⁻¹". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes "g⁻¹"? As written, it is impossible to determine the

metes and bounds of the claimed invention.

Claim 16 is rendered vague and indefinite by the use of the phrase “propyl paraben is between 0.25 and 0.25 g·l⁻¹”. It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes “between 0.25 and 0.25 g·l⁻¹”? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 24 is rendered vague and indefinite by the use of the phrase “US and/or European pharmacopeia test protocol”. It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes the “US and/or European pharmacopeia test protocol”, which is to be fulfilled? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-13, 18, 19, 21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Pritikin et al. (U.S. Patent 4,664,861).

The rejected claims are drawn to a method of producing a separation matrix with eliminated or reduced microbial content, comprising providing said separation matrix, microbially contaminated, in a housing or container; adding an aqueous antimicrobial

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preservation composition, which comprises at least one alkyl paraben, to said separation matrix in said housing or container; allowing said aqueous antimicrobial preservation composition to exert its effect in said housing or container until the number of colony forming units per g preservative composition is sufficiently reduced; and rinsing said aqueous antimicrobial preservation composition from said housing or container.

Pritikin et al. disclose a method of producing a matrix comprising the use of a fibrous tube in an aqueous bath to remove chemical impurities. The casing was then immersed in an aqueous preservative bath saturated with 1500 ppm of propyl paraben (see column 9, lines 15-21). Pritikin et al. disclose that the matrixes are inoculated with spores from multiple genera of molds, the matrixes treated with the paraben either showed no detectable mold growth or very slight growth (see column 9, lines 33-37 and 50-52). Moreover, Pritikin et al. disclose the use of esters selected from methyl, ethyl, propyl or butyl paraben (see column 6, lines 61-62). Pritikin et al. disclose that dissolution of propyl paraben in an alcoholic cosolvent improves the overall microbicidal activity. Propyl paraben have the most favorable solubility characteristics in propylene glycol (see column 7, lines 29-30).

Absent evidence to the contrary, and in light of the 112/2 rejections, the method of Pritikin et al. is identical to the claimed invention. The concentration of alkyl paraben necessarily decreases with increasing alkyl number, is necessarily between 0.25 and $0.25 \text{ g} \cdot \text{l}^{-1}$, and is necessarily allowed to exert its effect for at least 6 hours and until US and/or European pharmacopeia test protocol is fulfilled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 14, 15, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritikin et al. (U.S. Patent 4,664,861) as applied to claims 11-13, 18, 19, 21, 23 and 24 above.

The rejected claims are drawn to a method of producing a separation matrix with eliminated or reduced microbial content, comprising providing said separation matrix, microbially contaminated, in a housing or container; adding an aqueous antimicrobial preservation composition, which comprises at least one alkyl paraben, to said separation matrix in said housing or container; allowing said aqueous antimicrobial preservation composition to exert its effect in said housing or container until the number of colony forming units per g preservative composition is sufficiently reduced; and rinsing said aqueous antimicrobial preservation composition from said housing or container.

Pritikin et al. disclose a method of producing a matrix comprising the use of a fibrous tube in an aqueous bath to remove chemical impurities. The casing was then immersed in an aqueous preservative bath saturated with 1500 ppm of propyl paraben (see column 9, lines 15-21). Pritikin et al. disclose that the matrixes are inoculated with spores from multiple genera of molds, the matrixes treated with the paraben either

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showed no detectable mold growth or very slight growth (see column 9, lines 33-37 and 50-52). Moreover, Pritikin et al. disclose the use of esters selected from methyl, ethyl, propyl or butyl paraben (see column 6, lines 61-62). Pritikin et al. disclose that dissolution of propyl paraben in an alcoholic cosolvent improves the overall microbicidal activity. Propyl paraben have the most favorable solubility characteristics in propylene glycol (see column 7, lines 29-30).

Absent evidence to the contrary, and in light of the 112/2 rejections, the method of Pritikin et al. is identical to the claimed invention. The concentration of alkyl paraben necessarily decreases with increasing alkyl number, is necessarily between 0.25 and $0.25 \text{ g} \cdot \text{l}^{-1}$, and is necessarily allowed to exert its effect for at least 6 hours and until US and/or European pharmacopeia test protocol is fulfilled.

Pritikin et al. do not specifically disclose the concentration of methyl, ethyl and butyl paraben.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the amounts of alkyl paraben in Pritikin et al. because limitations such as the concentration of a paraben are being viewed as limitations of optimizing experimental parameters and is part of the ordinary capabilities of one skilled in the art.

Conclusion

6. No claims are allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
6/22/09

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

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